

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC IBird lyophilisate for suspension for chickens

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### Active substance:

Live, attenuated infectious bronchitis (IB) virus, strain 1/96, 2.8 – 4.3 log<sub>10</sub> EID<sub>50</sub>\* / dose

### Excipients:

For the full list of excipients, see section 6.1.

\*EID<sub>50</sub> = 50 % Embryo infective dose: the virus titre required to produce infection in 50% of the embryos inoculated.

## 3 PHARMACEUTICAL FORM

Lyophilisate for suspension.  
Yellowish white pellet.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Chickens

### 4.2 Indications for use, specifying the target species

For the active immunization of broiler and futurelayer chickens in order to reduce the detrimental effect on the ciliary activity and presence of virus in trachea resulting from the infection, which may be manifested in respiratory clinical signs. Protection was demonstrated by challenge with the 793/B strain, which is a representative strain of the 793/B group.

Onset of immunity: 3 weeks after one vaccination.

Duration of immunity: 6 weeks after one vaccination, except for future layers in which duration of immunity is 9 weeks after the first vaccination by spray route.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

Vaccinate healthy animals only.

### 4.5 Special precautions for use

#### Special precautions for use in animals

All chickens on a site should be vaccinated at the same time and within the same premises.

The vaccine strain may spread to non-vaccinated chickens. Vaccinated chickens may excrete the vaccine strain for up to 28 days or longer following vaccination.

Care should be taken to avoid spread of the vaccine virus from vaccinated chickens to pheasants and turkeys.

Cevac IBird is intended to protect chickens against respiratory disease caused by variant strains of infectious bronchitis virus belonging to the 793/B group and should not be used as a replacement for other IBV vaccines.

The product should not be used without a diagnosis being made that infection is caused by a strain of the 793/B group and after it has been established that the IBV virus group 793/B is epidemiologically relevant in this area. Care should be taken to avoid the introduction of the variant group into an area where it is not present.

Good animal husbandry, hygiene practices (e.g. cleaning and disinfection procedures, changing clothing and shoes for visitors) can effectively help to protect the environment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

The vials may be opened under water to avoid aerosol forming.

Personal protective equipment consisting of waterproof gloves and safety glasses should be worn when handling the veterinary medicinal product. Wash hands after using the product.

#### **4.6 Adverse reactions (frequency and seriousness)**

After vaccination with the product, no notable clinical signs were observed.

Slight tracheal rales were observed commonly in field trials which may persist for at least 10 days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

#### **4.7 Use during pregnancy, lactation or lay**

Layer chickens: the repeated use of Cevac IBird has been shown to be safe in layers during lay.

#### **4.8 Interaction with other medicinal products and other forms of interactions**

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Cevac Mass L by spray application in chickens from 1 day of age onwards.

After mixed administration with Cevac Mass L the duration of immunity in broiler chicken was shown to be 9 weeks.

No information is available on the safety and efficacy of Cevac IBird when mixed and administered with Cevac Mass L to hens during laying period.

The mixed products protect against strains belonging to 793/B and Massachusetts groups of IBV. The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately. Read the product information of Cevac Mass L before use.

Care should be taken to avoid spreading of the vaccine strains to other bird species, in particular when the vaccines are mixed. Simultaneous use of both vaccines may increase the risk of recombination of viruses and potential emergence of new variants. However, the chance of a hazard occurring has been estimated very low.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except Cevac Mass L. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

#### **4.9 Amounts to be administered and administration route**

Nebulisation use for broiler and future layer chickens

One dose of the vaccine should be administered by nebulisation use with coarse spray from 1 day of age. Older chickens can also be vaccinated by coarse spray.

Nebulisation method: The vaccine should preferably be dissolved in distilled water or alternatively in cool, clean chlorine free water. The appropriate number of vials should be opened under water. The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the chickens. This will vary according to the age of the chickens being vaccinated and the management system, but at least 200 ml of water per 1000 doses is suggested. The vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30-40 cm using a coarse spray providing droplet sizes in a range of 100-200 µm. The nebulisation use via coarse spray application is preferable when the chickens are sitting together in dim light. The spray apparatus should be free from sediments and corrosion traces or disinfectants.

For effective vaccine distribution, make sure that birds are closely confined together during spraying.

Depending on housing conditions, ventilation should be switched off during and after vaccination in order to avoid turbulences.

#### Drinking water use for future layer chickens

One dose of the vaccine should be administered by drinking water from 10 days of age. In order to maintain immunity, chickens may be revaccinated every 3 weeks. No studies were done to show protection during the laying period.

The vaccine should be dissolved in the drinking water. The amount of water should be calculated based on the average water consumption of the flock in the previous 4 days before vaccination. Calculate the amount of water needed, so that the vaccine is consumed within 2 hours. This amount should be approximately 30% of the daily intake.

Medication, disinfectants and chlorine must be removed from the drinking water 48 hours before vaccination.

Water should be withheld prior to vaccination to make the chickens thirsty. The period for water withdrawal is dependent on the climate. Water withholding should be kept as short as possible with a minimum of 30 minutes.

The vials should be opened under water. Use cool, clean water to dissolve the vaccine. For administration of the vaccine, as a general rule, dissolve 1000 doses in one litre per age in days up to a maximum volume of 20 litres per 1000 doses, or in hot weather, the quantity of water may be increased up to 40 litres per 1000 doses.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

No side effects other than those listed in paragraph "Adverse reactions" have been observed following the administration of ten times the recommended dose of vaccine.

#### **4.11 Withdrawal period(s)**

Zero days.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Immunologicals for aves/Domestic fowl/Live viral vaccines/ avian infectious bronchitis virus (IBV)  
ATCvet code: QI01AD07

To stimulate active immunity in chickens against avian infectious bronchitis virus, strain 1/96 belonging to the 793/B virus group.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Gelatine  
Lactose  
Sorbitol  
Sucrose  
Potassium dihydrogen phosphate  
Dipotassium hydrogen phosphate  
Water for injection

#### **6.2 Major incompatibilities**

Do not mix with any other veterinary medicinal product, except Cevac Mass L where it is marketed.

#### **6.3 Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

Shelf life after dilution according to directions: 2 hours

#### **6.4 Special precautions for storage**

Store and transport refrigerated (2°C – 8°C).

Do not freeze.

Protect from light.

## **6.5 Nature and composition of immediate packaging**

The vaccine is supplied in 3 and 10 ml clear glass vials of hydrolytic glass type I. The vial is closed with bromobutyl stoppers, and sealed with aluminium caps with plastic tear-off centres.

1 vial contains 500, 1000, 2500, 5000 or 10000 doses presented in a cardboard box with 1, 10 or 20 vials/ box.

Not all pack sizes may be marketed.

## **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale  
10, avenue de La Ballastière  
33500 Libourne  
France

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA10815/022/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 23 August 2013

Date of last renewal: 20 April 2018

## **10 DATE OF REVISION OF THE TEXT**

May 2019